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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/615,736 | 07/13/2000 | David Frederick Horrobin | P65773US0 | 4938 |

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EXAMINER

PESELEV, ELLI

ART UNIT PAPER NUMBER

1623

DATE MAILED: 11/23/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. _____

Applicant(s) _____

Examiner _____

Group Art Unit _____

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 11/09/01
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 16-41 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 16-41 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

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Claims 40-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 40-41 are directed to methods for treating or preventing any cardiovascular disorder or cerebrovascular disorder, any form of diabetes or pre-diabetes, any form of psychiatric disorder, any form of neurological or neurodegenerative disorder, any form of kidney disorder, any form of inflammatory or immunological disorder, any form of eye or hearing disorder, any form of obesity and any form of cancer. However, the specification fails to present any evidence that the claimed methods are useful in treatment and prevention of all the disorders listed in claims 40-41. Since there is no known methods that are useful in the treatment and prevention of all the diseases encompassed by claims 40-41, there is a good reason to doubt that the claimed methods are useful in treatment and prevention of any diseases set forth in claims 40-41.

Applicant's arguments filed November 9, 2001 have been fully considered but they are not persuasive.

Applicants contend that most of the diseases and disorders as recited show some response to EFA treatment. This argument has not been found persuasive because applicants have not provided any evidence showing said response. Further, note that claims 40-01 also encompass prevention of said diseases and disorders.

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Claims 16-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methyltetrahydrofolate, does not reasonably provide enablement for a compound related to folic acid with similar biological activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The only compound disclosed by the specification that is related to folic acid is methyltetrahydrofolate. It would take an undue amount of experimentation to determine which other compounds that are related to folic acid will be useful in the instant invention.

Applicant's arguments filed November 9, 2001 have been fully considered but they are not persuasive.

The specification fails to define what is encompassed by compounds related to folic acid. Therefore it cannot be ascertained which of the known or unknown compounds are encompassed by said terminology.

Claims 16-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terminology "a compound related to folic acid biological activity similar to folic acid" (claim 16) renders the claims indefinite because said terminology is unclear.

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Claims 16-41 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over the European Patent No. 0,305,097, the European Patent No. 0,198,804 or WO 99/03482 for the reasons set forth in the Office Action of August 10, 2001.

Applicant's arguments filed November 9, 2001 have been fully considered but they are not persuasive.

The instant claims contain the term "comprising". Therefore, the claimed formulations are open-ended and encompass any additional compounds, including those set forth by the prior art of record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

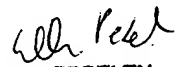
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (703) 308-4616. by he examiner can normally be reached on weekdays from 8.30 a.m. to 5.00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached on (703) 308-1701. by he fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


ELLI PESELEV
PRIMARY EXAMINER
GROUP 1800